



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/719,415

11/21/2003

Dusan Pavcnik

PA-5360-RFB

3409

9896 7590 12/22/2008
COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER

PRONE, CHRISTOPHER D

ART UNIT	PAPER NUMBER
----------	--------------

3738

MAIL DATE	DELIVERY MODE
-----------	---------------

12/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/719,415	Applicant(s) PAVCNIK ET AL.	
	Examiner CHRISTOPHER D. PRONE	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13, 15 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-12, 14, 16-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 9-11, 14, 17, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,865,723 Love in view of United States Patent 5,891,193 Robinson et al and further in view of Banas et al USPN 6,214,039 B1

Love discloses the invention substantially as claimed comprising expandable first inner stent 16, expandable second outer stent 14, and a tissue graft layer 12 comprising an extra cellular matrix material collagen disposed on the first stent and under the second. Love also discloses that the stent may comprise a plurality of circumferential segments and a plurality of tie bars shown in figure 9. In regards to claims 17, figure 2 of Love shows that the outside diameter of the first stent is greater than the inside diameter of the second stent. In regards to claim 18 Love further discloses that the first and second stents have equivalent inside and outside diameters (7:25-37).

However, Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft or that the implant is held together without solely by compressive forces.

Robinson teaches the use of a tubular implant comprising a tissue graft 20 and an inner expandable stent member having anchors that extend beyond the grafts distal and proximal ends in the same field of endeavor for the purpose of securely anchoring the distal and proximal ends of the implant to the operation site.

Banas teaches use of an implant comprising a stent and a graft that retains their positioning during and after implantation without adhesives or sutures, solely by compressive forces in the same field of endeavor for the purpose of eliminating the use of adhesives

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Love have stent anchor extensions on both tubular member that extend beyond the graft ends as taught by Robinson and to eliminate the use of adhesives in light of compressive forces as taught by Banas in order to better anchor the implant to the vessel without the use of glue

Claims 4, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love in view of Robinson and Banas and further in view of United States Patent 6,358,284 B1 Fearnot et al and Banas et al USPN 6,214,039 B1.

The combination of Love in view of Robinson and Banas discloses the invention substantially as claimed being disclosed above. However, the combination does not disclose that the tissue graft comprises multiple layers of submucosa.

Fearnot teaches the use of tubular grafts comprising layers of submucosa sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the stent graft of Love as modified by Robinson in order to provide enhanced repair of damaged or diseased host tissues.

Claims 1, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 5,628,788 Pinchuk in view of United States Patent 6,358,284 B1 Fearnot et al and further in view of Banas et al USPN 6,214,039 B1.

Pinchuk discloses the invention substantially as claimed being a double-layered stent graft wherein the inner stent is smaller than the outer stent and the ends of each layer are at least coincident as seen in figures 3-9. However, Pinchuk does not disclose that the graft comprises multiple layers of tissues or that they are held together solely by compressive forces.

Fearnot teaches the use of tubular grafts comprising layers of submucosa tissue sheets in the same field of endeavor for the purpose of providing enhanced repair of damaged or diseased host tissues.

Banas teaches use of an implant comprising a stent and a graft that retains their positioning during and after implantation without adhesives or sutures, solely by compressive forces in the same field of endeavor for the purpose of eliminating the use of adhesives

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the submucosa tissue graft layers as taught by Fearnot with the double layered stent graft of Pinchuk and to eliminate the use of adhesives in

Art Unit: 3738

light of compressive forces as taught by Banas in order to provide enhanced repair of diseased host tissues and better anchoring and expansion and to better anchor the implant to the vessel without the use of glue

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738